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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,462	07/19/2001	Beth A. Burnside	550750	7386

27162 7590 06/24/2002

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EXAMINER	
BERMAN, ALYSIA	
ART UNIT	**PAPER NUMBER**
1617	8

DATE MAILED: 06/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/807,462	Applicant(s) BURNSIDE ET AL.	
	Examiner Alysia Berman	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 October 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Receipt is acknowledged of the declaration filed October 1, 2001 and the information disclosure statement, preliminary amendment and terminal disclaimer filed October 30, 2001. Claims 1-18 have been canceled. Claims 19-46 have been added and are pending.

Specification

2. The disclosure is objected to because of the following informalities: the disclosure recites, "For example,." at page 3, line 26.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 19-29, 42 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide sufficient guidance as to what is required in the instantly claimed dosage forms to provide the plasma concentration levels instantly claimed. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "delayed release" dosage forms, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. The

specification does not provide sufficient information to practice the claimed invention without undue experimentation.

5. Claims 30-41 and 44-46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not provide sufficient guidance as to what is required in the instantly claimed pharmaceutical to provide an immediate release dose and a delayed release does upon oral administration. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all pharmaceuticals comprising pharmaceutically active amphetamine salts, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. The specification does not provide sufficient information to practice the claimed invention without undue experimentation.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 19-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. The term "delayed" in claims 19-23, 25, 26 and 29-40 is a relative term which renders the claim indefinite. The term "delayed" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one

of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

9. Claims 22-24, 27-31, 34, 36, 39 and 42-46 recite the limitation "the amphetamines". There is insufficient antecedent basis for this limitation in the claim.

10. Claims 27, 28, 30-41 and 44-46 are indefinite because it is unclear what amount of amphetamine is needed to provide and effective level. Without an explanation of what is the desired goal is, an effective level in order to accomplish that goal cannot be determined. The metes and bounds of the claims cannot be determined.

11. Claims 30-41 and 44-46 are indefinite because it is unclear what Applicant intends to require by the phrase "releasing said amphetamine as an immediate release dose and as a delayed release dose." Does Applicant intend that the pharmaceutical of the claims contain separate and distinct immediate release dosage forms and delayed release dosage forms?

12. Claims 20, 21, 23, 25, 26, 32, 33, 37 and 38 are rejected because the delayed release dose in these claims is not defined with any chemical or physical characteristic, but only by functional properties. A claim to a material defined solely in terms of what it can do, or a property thereof, does not particularly point out the claimed invention. Thus, the scope is indefinite. See *ex parte Pulvari* (POBA 1966) 157 USPQ 169.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Instant claims 19-29, 42 and 43 are drawn to a composition comprising

a. An immediate release dosage form containing amphetamine salts and

b. A delayed release dosage form containing amphetamine salts.

16. Claims 19-29, 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,312,388 (388).

US '388 discloses pharmaceutical dosage forms that provide an immediate release of an active agent followed by a delayed pulse delivery of an active agent (abstract). For amphetamine salts see column 7, lines 66-68. For enteric coatings see column 15, lines 16-19. For pH dependent coating see Eudragit® L 100-55 in Example 2 at column 16. For pH independent coating see cellulose acetate/polyethylene glycol at column 17, lines 23-24. At column 3, lines 25-51 US '388 discloses that the delayed pulse dosage form releases the entire active agent from the formulation. For release of

active agent from the delayed release dosage form at about 6 hours from administration see Example 6 at column 17.

US '388 does not teach the plasma concentration of the amphetamines after release, release of the amphetamines from (b) within about 60 minutes (claims 22, 23, 29), or initiation of release of amphetamine from (b) in from 4-6 hours after administration (claim 24).

The products of the prior art contain the same components as instantly claimed. One of ordinary skill in the art would expect a product that is the same as instantly claimed to exhibit the same properties and characteristics. Burden is shifted to Applicant to show that the prior art product does not provide the same plasma concentration levels and release profiles instantly claimed.

It is within the skill in the art to select optimal parameters in a composition in order to achieve a beneficial effect. *In re Boesch*, 205 USPQ 215 (CCPA 198). It would have been obvious for one skilled in the art to vary the proportions of components in a composition to arrive at the best compositions for the intended purpose. "It is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Only if the "results optimizing a variable" are "unexpectedly good" can a patent be obtained for the claimed critical range. *In re Antonie*, 559 F.2d 618, 620, 195 USPQ 6, 8 (CCPA 1977); see also *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (in banc). Absent evidence to the contrary, it is within the skill in the art to select optimal amounts

and combinations of components in the dosage forms in order to achieve the desired release profile and plasma concentrations.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '388 selecting optimal parameters in order to obtain desired release profiles and plasma concentrations.

17. Claims 30-41 and 44-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,312,388 (388) in combination with US 5,885,998 (998).

US '388 teaches all the limitations of the claims as stated above. It does not teach treating ADHD. US '998 teaches that it is known to administer dextroamphetamine sulfate for treatment of ADHD (col. 3, lines 22-27).

It would have been obvious to one of ordinary skill in the art at the time of the invention to orally administer the pharmaceutical dosage form of US '388 containing amphetamine salts for the treatment of ADHD as taught by US '998 expecting to provide an immediate delivery of active agent.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on 703-308-4612. The fax phone numbers

for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

Alysia Berman
Patent Examiner
June 10, 2002

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